IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

PFIZER, INC.,	)	
	)	
Plaintiff and	)	
Counterclaim Defendant,	)	
	)	
v.	)	02: 02cv1628
	)	
MYLAN LABORATORIES, INC. and	)	
MYLAN PHARMACEUTICALS, INC.,	)	
	)	
Defendant and	)	
Counterclaim Plaintiffs.	)	

MEMORANDUM OPINION AND ORDER OF COURT

November 2, 2005

Presently before the Court for disposition is the MOTION FOR PARTIAL SUMMARY JUDGMENT ON INVALIDITY OF CLAIMS 1-11 OF U.S. PATENT NO. 4,572,909, with brief in support filed by Defendants Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively referred to as "Mylan") (*Document Nos. 78 and 79*), the Memorandum in Opposition filed by Pfizer, Inc. (*Document No. 106*), and the Reply Brief filed by Mylan (*Sealed Document No. 118*). For the reasons that follow, the Motion will be denied.

BACKGROUND

Plaintiff Pfizer, Inc. ("Pfizer") is a pharmaceutical company whose two patents cover an amlodipine besylate product sold under the trade name, Norvasc®. The active chemical compound in Norvasc® is amlodipine, a compound of the class known as 1,4-dihydropyridines. The amlodipine compound in Norvasc® is a salt, amlodipine besylate.

Amlodipine is protected by United States Patent No. 4,572,909 ("the '909 patent"), which covers a genus of compounds, including a specific claim (claim 8) to amlodipine,

pharmaceutical formulations of the claimed compounds, and methods of treating humans for cardiovascular disease by administering the claimed compounds. The application for the '909 patent was filed originally on March 11, 1982, in Great Britain by Pfizer's British subsidiary. On February 3, 1983, the parent application for the '909 patent was filed in the United States claiming the UK filing date of March 11, 1982, as its priority date under 35 U.S.C. § 119. On February 3, 1984, a continuation-in-part application was filed in the United States, and that application issued as the '909 patent on February 26, 1986.

The second patented invention utilized in Norvasc® is the besylate salt of amlodipine, and specific pharmaceutical formulations of the besylate salt of amlodipine. Amlodipine besyalte salt is protected by United States Patent No. 4,879,303 ("the '303 patent"). A patent application for amlodipine besylate salt was filed in the UK on April 4, 1986, and filed in the United States on March 25, 1987. A continuation application was filed on October 13, 1988, and the patent issued on November 7, 1989.

Pursuant to the Patent Term Restoration Act, 35 U.S.C. § 156, the term of the '909 patent was extended by the Patent and Trademark Office ("PTO") to July 31, 2006, to restore the time lost from the patent term while the drug was undergoing FDA trials and approval. In addition, pursuant to 21 U.S.C. § 355(a), Pfizer conducted pediatric trials and Norvasc® was awarded six months "pediatric exclusivity." Thus, the expiration date of the '909 patent is January 31, 2007. Due to a similar six-month pediatric exclusivity period, the '303 patent will expire on September 28, 2007.

On May 22, 2002, Mylan filed an Abbreviated New Drug Application ("ANDA") in which it sought approval to sell generic amlodipine besylate. By letter dated July 23, 2002,

Mylan certified pursuant to 21 C.F.R. 314.94(a)(12)(i)(A)(4) (hereinafter referred to as a "paragraph IV certification") that it was seeking approval to market its generic copy of Norvasc® prior to the expiration of the '909 and '303 patents. The application stated that to the best of Mylan's knowledge neither the '909 nor the '303 patents would be infringed by the manufacture, use or sale of the proposed generic amlodipine besylate.

On September 20, 2002, Pfizer filed this patent infringement action pursuant to 35 U.S.C. § 271(e), which makes it an act of infringement to file an ANDA for a drug claimed in a patent. Mylan's defenses and counterclaims include, *inter alia,* the allegation that the '909 patent is invalid based on double patenting. Specifically, Mylan claims that certain claims of the '909 patent are invalid for double-patenting over U.S. Patent 4,430,333 (the " '333 patent"), an earlier patent issued to Pfizer.[4]

At issue in the instant motion for partial summary judgment is the validity of the '909 patent.

STANDARD OF REVIEW

The general standard for summary judgment applies in a patent case. *See Brown v. 3M*, 265 F.3d 1349, 1350 (Fed. Cir. 2001) (general summary judgment standard applies to invalidity). Accordingly, the burden is on the moving party to establish that there are no genuine issues of material fact in dispute and that it is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986). A court

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[4] On March 14, 1981, Pfizer filed a patent application which covered a genus of compounds, including UK-46,129, which was later filed in the United States on March 11, 1982. The '333 patent includes compound, composition, and method of treatment claims. The '333 patent has now expired.

must grant summary judgment if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact . *Celotex Corp v. Catrett,* 477 U.S. 317, 325 (1986). A dispute regarding a material fact is genuine " if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson,* 477 U.S. at 248.

When a party challenges a patent's validity, the court begins with the statutory presumption of validity. 35 U.S.C. § 282 ("A patent shall be presumed valid."). Accordingly, "the burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." *Id*. Invalidity must be shown by clear and convincing evidence. *Robotic Vision Sys. v. View Eng'g, Inc.,* 189 F.3d 1370, 1377 (Fed. Cir. 1999). This presumption of validity is never weakened, and the burden of proving invalidity does not shift from the party asserting invalidity. *Imperial Chemical Industries, PLC v. Danbury Pharmacal, Inc.,* 745 F. Supp. 998, 1004 (D. Del. 1990) (*citing ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1574-75 (Fed. Cir. 1984) (other citations omitted)). The burden of going forward with evidence rebutting invalidity may shift to the patentee only after the party asserting invalidity has demonstrated a legally sufficient *prima facie* case of invalidity. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc*., 776 F.2d 281, 291 (Fed. Cir. 1985). If the party asserting invalidity has established a legally sufficient case of invalidity, the court then examines all of the evidence of invalidity together with all of the evidence rebutting invalidity, and determines whether there is clear and convincing evidence of invalidity. *Id.* at 291-92.

It is with these principles in mind that the Court turns to the merits of the motion before it.

Discussion

Mylan argues that it is entitled to partial summary judgment because Claims 1-11 of the '909 patent are "inherently anticipated by Claims 1-4 and 8-10 of the '333 patent because practicing the '333 patent claims necessarily and inevitably produces the metabolites amlodipine and UK-48,265." Mylan Br. at 10.

Pfizer, not surprisingly, strenously argues that the practice of the claims of the '333 patent does not necessarily result in the production of a compound claimed by the '909 patent claims, i.e., namely, amlodopine and UK-48,265. In support of its argument, Pfizer argues that "one could practice method claim 10 of the '333 patent by using a 1-naphtyle compound and it would never metabolize to amlodipine." Pfizer Br. at 21-22 (citing Castagnoli Tr. 156).

The judicially-created doctrine of obviousness-type double patenting prohibits parties from in effect extending their patent exclusion rights by filing a later patent with claims that cannot be considered patentably distinct from claims previously asserted in a commonly-owned earlier patent. *Eli Lilly and Co. v. Barr Laboratories, Inc*., 251 F.3d 955, 967 (Fed. Cir. 2001) (citation omitted). In reviewing a double patenting claim:

> a court construes the claim in the earlier patent and the claim in the later patent and determines the differences. Second, the court determines whether the differences in subject matter between the two claims render them patentably distinct. A later claim that is not patentably distinct from an earlier claim in a commonly owned patent is invalid for obvious-type double patenting. A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim.

Id. at 968 (citations omitted). In assessing obviousness, only the claims are to be compared, and the Court neither examines motivation to combine prior art references nor objective

standards of non-obviousness as with obviousness inquiries under 35 U.S.C. § 103. *Geneva Pharmaceuticals, Inc. v. Glaxosmithkline PLC,* 349 F.3d 1373, 1378 (Fed. Cir. 2003).

Double patenting, as an invalidity defense, must be proved by the moving party by clear and convincing evidence, *Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1580 (Fed. Cir. 1991) ("a heavy and unshifting burden"), and is considered a question of law because it relies solely on the terms of what has been claimed in the two patents at issue, like claim construction. *Georgia-Pacific Corp. v. United States Gypsum Co.*, 195 F.3d 1322, 1326 (Fed. Cir. 1999). Thus, the court cannot rely on the earlier patent's specification as prior art in evaluating double patenting, though the specification may be used as in claim construction to evaluate the scope of the claims at issue. *Geneva,* 349 F.3d at 1385.

The first step in the analysis of the validity issues raised by the instant motion for partial summary judgment is claim construction, that is, the determination of the ordinary and customary meaning that would be attributed to the claim terms by those skilled in the art. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff'd,* 517 U.S. 370 (1996). The construction of the relevant claims of the '909 and '333 patents appears to be undisputed.[5] Thus, in construing the relevant claims, the Court will rely upon the plain language of the claims and, where the language is unclear, the specifications.

The next step in the analysis is for the Court to determine whether the differences in subject matter between the claims render the claims patentably distinct. *Georgia-Pacific Corp. v. United States Gypsum Co.*, 195 F.3d 1322, 1327 (Fed. Cir. 1999), *cert. denied*, 531 U.S. 816

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[5] The Court notes that the parties have not requested a Markman hearing on the relevant claims of the '909 patent.

(2000). A later claim that is not patently distinct from an earlier claim in a commonly owned patent is invalid for nonstatutory double patenting. *In re Berg,* 140 F.3d 1428, 1431 (Fed. Cir. 1998). "A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim." *Eli Lilly & Co. v. Barr Labs, Inc.,* 251 F.3d 955, 968 (Fed. Cir. 2001).

"A reference is anticipatory if it discloses every limitation of the claimed invention either explicitly or inherently . . . . A reference includes an inherent characteristic if that characteristic is the 'natural result' flowing from the reference's explicitly explicated limitations." *Id.* at 970. If the later claim is anticipated by the earlier claim, there can be no patentable distinction, as a matter of law. *Id.* In order to receive patent protection the newly claimed invention must be novel and distinct from all previously claimed patented inventions the holder owns. *Id.*

As stated *supra*, Mylan argues that "the undisputed evidence shows the production of metabolites UK-46,265 and amlodipine upon administration of UK-46,129 ['333]. . . . Thus, the natural metabolic production of the claimed metabolites, here amlodipine and UK-48,265, flow from practicing claims directed to a parent compound, here UK-46,129." Mylan Br. at 11.

In support of its position, Mylan relies, *inter alia,* on *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373 (Fed. Cir. 2003), in which the Federal Circuit Court held that "the metabolite of the prior art [patent] is the same compound as the claimed invention." In *Schering,* it was undisputed that after clinical trials involving 864 humans and 21 clinical studies, no human had been found that did not metabolize the [prior art compound] to the [same

compound as the claimed invention.]" Thus, the parties agreed that the claims at issue covered a metabolite of the prior art patent.

In rebuttal, Pfizer argues, that "the facts show that the practice of claims of the '333 patent does *not necessarily result* in the production of a compound claimed by the '909 patent claims." Pfizer Br. at 20 (emphasis in original). In the alternative, Pfizer argues that "even assuming *arguendo* that the use of UK-46,129 claimed in the '333 patent in animals would always and necessarily result in the production of UK-48,265 and amlodipine because of their formation of metabolites, amlodipine and UK-48,265 are indisputably not *claimed* in the '333 patent." *Id*. at 19 (emphasis in original).

Further, Pfizer argues that the '333 patent describes a genus of 1,4-dihydropyridine compounds that are either secondary or primary amines - not tertiary amines as in the '333 patent. All of the compounds in the '333 patent have a tertiary amine substituent at the 2-position of the molecule.

Unlike the parties in the *Schering* case, the parties in the present case do not agree that the practice of claims of the '333 patent necessarily result in the production of a compound claimed by the '909 patent claims.

Therefore, based on the record upon which summary judgment is to be determined, the Court finds and rules that Mylan has not come forward with clear and convincing evidence that claims 1-11 of the '909 patent were anticipated by the '333 patent. Specifically, there are genuine issues of material fact, due to competing expert opinions, as to what is disclosed and claimed by the '333 patent. Therefore, summary judgment as to whether claims 1-11 of the '909 patent are anticipated by the '333 patent is not appropriate at this time.

CONCLUSION

For the reasons stated above, the Motion for Partial Summary Judgment on Invalidity of Claims 1-11 of U.S. Patent No. 4,572,909 filed by Defendants Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. will be denied.

An appropriate Order follows.

McVerry, J.

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ORDER OF COURT

AND NOW, this 2nd day of November, 2005, in accordance with the foregoing Memorandum Opinion, it is hereby **ORDERED**, **ADJUDGED, AND DECREED** that the Motion for Partial Summary Judgment on Invalidity of Claims 1-11 of U.S. Patent No. 4,572,909 filed by Defendants Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. is **DENIED.**

BY THE COURT:

s/Terrence F. McVerry
United States District Court Judge

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